DEC 21 2001

Wiener lab.
Especialidades para Laboratorios Clínicos
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Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K011953 **"**

Introduction	According to the requirements of 21 CFR 862.1580, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.
1) Submitter Name, Address, Contact	Wiener Laboratorios S.A.I.C. Riobamba 2944 2000 – Rosario – Argentina Tel: 54 341 4329191 Fax: 54 341 4851986 Contact person: Viviana Cétola Date Prepared: June 04, 2001

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510(k) Summary, Continued

2) Device name

Proprietary name: WIENER LAB. GLICEMIA ENZIMATICA AA

Common name: Glucose test system.

Classification name: Glucose oxidase, glucose as per 21CFR section 862.1345.

Device Class II

3) Predicate Device

We claim substantial equivalence to the currently marketed Data Medical Associates, Inc. (DMA) GLUCOSE (Oxidase) test system.

4) Device description

End point method.

The Wiener lab. Glicemia enzimatica AA is based on the following reaction system:

$$\text{Glucose} + O_2 + H_2O \xrightarrow{\text{GOD}} \text{Gluconic Acid} + H_2O_2$$

$$2\,H_2O_2 + \text{4-AP} + \text{4-Hydroxybenzoate} \xrightarrow{\text{POD}} \text{red quinonimine}$$

The amount of glucose is determined by measuring the absorbance of this pigment

GOD (glucose oxidase)
POD (peroxidase)
4-AP (4-aminophenazone).

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5) Intended use

The GLICEMIA ENZIMATICA AA test system is intended to be used in the quantitative determination of glucose in human serum and plasma on both manual and automated systems. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

6) Equivalencies and differences

The WIENER LAB. GLICEMIA ENZIMATICA AA test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed DMA GLUCOSE (oxidase) test system.

The following table illustrates the similarities and differences between the WIENER LAB. GLICEMIA ENZIMATICA AA test system and the currently marketed DMA GLUCOSA test system.

	DMA Test System	**WIENER LAB. Test System**
Intended use	Quantitative determination of glucose in human serum and plasma.	
Test principle	End point method. The principle is based on the following reaction system: $\text{Glucose}+O_2+H_2O \xrightarrow{\text{GOD}} \text{Gluconic Acid} + H_2O_2$ $2\ H_2O_2+\text{4-AP}+\text{4-Hydroxybenzoate} \xrightarrow{\text{POD}} \text{red quinonimine}$	
Essential Components	GOD - POD - Mutarotase - 4-AP Hydroxybenzoate	GOD - POD - 4-AP Hydroxybenzoate

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Calibrator and Serum Controls	Available - provided separately	
Instability or deterioration of reagents	Blank Absorbance > 0.300. Abnormal values of controls. Precipitated or hazy standard.	Blank Absorbance > 0.160. Abnormally low Standard Absorbance.
Sample	Human serum, heparinized plasmas, potassium oxalate/fluoride and EDTA/fluoride plasmas	
Working Temperature Range	37°C	Manual: 15 - 37°C Automated: 37°C
Stability of final color	Not specified	30 minutes
Wavelength of reading.	505 nm	
Calibration	Single point	
Linearity	1000 mg/dl	500 mg/dl
Minimum detection limit	1.4 mg/dl	0.544 mg/dl
Expected values	75 - 113 mg/dl (70 – 105 mg/dl)	70 – 110 mg/dl (70 - 105 mg/dl)
Intra-assay precision	Normal Serum Control: CV = 0.66% Abnormal Serum Control: CV = 0.58%	Normal Serum Control: CV = 1.39% Abnormal Serum Control: CV = 1.11%

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Inter-assay precision	Normal Serum Control: CV =1.22% Abnormal Serum Control: CV = 0.91%	Normal Serum Control: CV =1.92% Abnormal Serum Control: CV = 1.62%
Sterility conditions	Not required	

7) Conclusion Above mentioned data show substantial equivalency to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 2001

Dr. Viviana Cétola
QC/QA Manager
Weiner Laboratorios S.A.I.C.
2944 Riobamba
Rosario, Santa Fe,
Argentina

Re: k011953
Trade/Device Name: Glicemia enzimatica AA
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA
Dated: October 1, 2001
Received: October 9, 2001

Dear Dr. Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011953

Device Name: Wiener lab.
Glicemia enzimática AA

Indications For Use:

The "Wiener lab. Glicemia enzimática AA" test system is intended to be used in the quantitative determination of glucose in human serum and plasma on both manual and automated systems. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011953

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___

(Optional Format 1-2-96)